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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NTP Monograph on the Systematic Review of Evidence of Long-Term Neurological Effects Following Acute Exposure to the Organophosphorus Nerve Agent Sarin; Availability of Document; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces availability of the Draft NTP Monograph on the Systematic Review of Evidence of Long-Term Neurological Effects Following Acute Exposure to the Organophosphorus Nerve Agent Sarin for public comment prior to peer review. In partnership with the National Institutes of Health (NIH) Countermeasures Against Chemical Threats (CounterACT) Program, the Office of Health Assessment and Translation (OHAT), Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), conducted a systematic review to evaluate the evidence of long-term neurological damage in humans after acute, sub-lethal exposure to sarin. The date for the peer review is not yet set; however, it is anticipated to occur in early 2019. The peer-

review meeting will be held by webcast only and open to the public; registration will be required for attendance by webcast and to present oral comments. Information about the meeting and registration is available at <https://ntp.niehs.nih.gov/go/36051>.

DATES:

Meeting: When set, the peer-review meeting date will be announced on the meeting web page at <https://ntp.niehs.nih.gov/go/36051> along with deadlines for registration to present oral public comments and to view the webcast. The anticipated timeframe is early 2019.

NTP will also announce the meeting date in an email Listserv notice. Persons can subscribe to news updates at

https://tools.niehs.nih.gov/webforms/index.cfm/main/formViewer/form_id/361.

Document Availability: The draft NTP monograph should be available by December 5, 2018, at <https://ntp.niehs.nih.gov/go/36051>.

Written Public Comment Submissions: Deadline is January 17, 2019.

Registration for Oral Comments: Please monitor the meeting web page at <https://ntp.niehs.nih.gov/go/36051> for updates pertaining to the oral public comment registration deadline.

Registration to View Webcast: Please monitor the meeting web page at <https://ntp.niehs.nih.gov/go/36051> for updates pertaining to the webcast registration deadline.

ADDRESSES:

Meeting Location: Webcast.

Meeting Webpage: The draft NTP monograph, preliminary agenda, registration, and other meeting materials will be available at <https://ntp.niehs.nih.gov/go/36051>.

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Ms. Camden Byrd, ICF, 2635

Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293-1660, Fax: (919) 293-1645, Email: NTP-Meetings@icf.com.

SUPPLEMENTARY INFORMATION:

Background: OHAT serves as an environmental health resource to the public and to regulatory and health agencies. This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels.

Sarin is a highly toxic organophosphorus nerve agent that was developed for chemical warfare during World War II and continues to be used as a weapon. The draft NTP monograph presents the results of the systematic review to evaluate the evidence for long-term neurological effects in humans following acute, sub-lethal exposure to sarin with consideration of human, experimental animal, and mechanistic data.

Long-term neurological effects of acute exposure to sarin are not well characterized. Previous reviews of potential health effects of sarin have generally not assessed individual study quality or considered multiple evidence streams (human, animal, and mechanistic data). In addition, the interpretation of effects of sarin in some previous reviews was compounded by concurrent exposure to multiple chemicals, such as assessments of health effects in military personnel during the Gulf War or other conflicts.

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Please monitor the meeting web page at <https://ntp.niehs.nih.gov/go/36051> for updates pertaining to the webcast registration deadline. Individuals with disabilities who need accommodation to view the webcast should contact Camden Byrd by phone: (919) 293-1660 or email: NTP-Meetings@icf.com. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

Public Comment Registration: NTP invites written and oral public comments on the draft NTP monograph that address scientific or technical issues. Guidelines for public comments are at

https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

The deadline for submission of written comments is January 17, 2019. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and

sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific or technical issues will be forwarded to the peer-review panel and NTP staff prior to the meeting.

The agenda will allow for one oral public comment period (up to 12 commenters, up to 5 minutes per speaker). The deadline for registration to provide oral comments will be announced at <https://ntp.niehs.nih.gov/go/36051> after the meeting date is set. Registration will be on a first-come, first-served basis. Each organization will be allowed one time slot. Oral comments will be presented by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Commenters will be notified approximately one week before the peer-review meeting about the actual time allotted per speaker.

If possible, oral public commenters will be asked to send a copy of their slides and/or statement or talking points to Camden Byrd by email: NTP-Meetings@icf.com by the registration deadline.

Meeting Materials: The draft NTP monograph and preliminary agenda will be available on the NTP website at <https://ntp.niehs.nih.gov/go/36051>. The draft NTP monograph should be available by December 5, 2018. Additional information will be posted when available or may be requested in hardcopy, contact Camden Byrd by phone: (919) 293-1660 or email: NTP-Meetings@icf.com. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website.

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an “as needed” basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Camden Byrd by email: NTP-Meetings@icf.com. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: November 28, 2018.

Brian R. Berridge,

Associate Director,

National Toxicology Program.

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